Applicants' Response

The examiner's response includes two sections: (1) rejection of the claims under 35 USC § 102 and (2) rejection of the claims under 35 USC § 103. Applicants respond below to each of these sections.

35 USC § 102 in view of Tweden

Claims 1, 3, 6, 7, 11-18, 20, 23, 24, 28-32, 34, 37, 38, 42-50, 52, 55, 56, 60-67 were rejected under 35 USC § 102(e) as being anticipated by US 7,008,397 to Tweden et al. In the specification and figures, Tweden was cited for disclosing the device claimed by the Applicant. The Examiner indicated that with regard to claims 1, 18, 32, and 50, Tweden discloses a medical shunt in the shape of a hollow cylinder 20, forming a conduit 12 therein (see column 3, lines 60-67) . The conduit has open ends 28, 30 that receive and discharge body fluids (see column 4, lines 1-9). The shunt may comprise occlusion-resistant materials deployed in a delivery agent (such as a knitted cloth) that resist occlusion of the shunt (see column 1, lines 43-54, and column 17, lines 50-60).

With specific regard to claims 32 and 50, the Examiner indicates to see columns 15-17 for Tweden's disclosure of preparing or making the disclosed shunt, column 18 for Tweden's disclosed method of inhibiting occlusion by implanting the shunt and allowing the drugs to elute from the shunt.)

With regard to claims 3, 20, 34, and 52, Tweden was cited for disclosing that the shunt may be made of a low-density polyethylene (see column 4, lines 50-55).

With regard to claims 6, 23, 37, and 55, Tweden was cited for disclosing that the shunt may incorporate anticoagulants (see column 7, lines 39-40).

With regard to claim 7, 24, 38, and 56, Tweden was cited for disclosing that the shunt may incorporate compounds containing silver (see column 8, lines 39-40).

With regard to claims 11-13, 16, 42-45, 48, 60-63, and 66, Tweden was cited for disclosing that the drugs incorporated as a part of the shunt may cover the entire shunt or portions thereof (see column 18, lines 35-38). Tweden's disclosure that a therapeutic agent is in "at least a partial covering" relationship to at least a first portion of the shunt indicates that the therapeutic agent may uniformly cover the entire shunt. Lines 35-48 of column 18 indicate that different therapeutic materials may be used non-uniformly in different regions of the shunt. (See also Tables 1-3 setting forth the distribution of therapeutic agents in proximal and distal portions of the shunt.)

With regard to claims 14-15, 28, 29, 30, 46, 37, 64, and 65, Tweden was cited for disclosing that the therapeutic materials may be incorporated in the shunt via various delivery devices and in different amounts in different locations, including a knitted or woven cloth (see column 17, lines 50-60, and column 18, lines 35-48).

With regard to claims 17, 31, 49, and 67, applicant's limitations were regarded to amount to a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitations. See MPEP 2114 . In the instant case, Tweden was specifically indicated for disclosing that different therapeutic agents may be deployed on different portions of the shunt. Inherent differences in the physical properties of the therapeutic materials may result in differing release rates between the differing materials. Therefore, the Tweden device was indicated to meet the limitations of the claim.

Applicants draw the attention of Examiner to key aspects of the Tweden et al. device and distinguish these aspects over the claimed invention (as amended).

First, Applicants wish to point that the device of Tweden et al. is directed to a cardiac implant that redirects the flow of blood from the myocardium to the vasculature. See figure 1 and related text.

> Column 4, lines 15-17 – "The first portion 26 is dimensioned to extend from the vasculature 36 through the myocardium 32 and into a heart chamber 38.

As such, Tweden's cardiac implant device needs to be constructed as a solid conduit for carrying blood from the heart chamber to the vasculature – if not the blood would leak into the surrounding tissue (see Tweden's Figures 1-6). Applicants distinguish their invention over that of Tweden et al. in that the claims are directed to a shunt having a plurality of apertures at the proximal end of the device. Such a device could not function as the conduit described by Tweden et al. because it could not deliver blood flow from the heart to the vasculature under the pressures developed in the heart without it leaking out into the tissue (see aperatures in Applicants Figures 2-6, in contrast to Tweden's solid conduit in Figures 1-6).

Another distinction between the claim invention and that of Tweden et al. is that Tweden et al. specifically indicates having an external wrapping of material around the main conduit. The purpose of the external wrapping is to facilitate tissue in growth to stabilize the conduit:

> Column 4, lines 31-35 – "The material 44 surrounds the exterior of the conduit 12 and may be a polyester woven cuff 45 or sintered metal to define pores into which tissue growth from the myocardium 32 may occur."
>
> Column 4, lines 58-60 – "The implant 60 includes a sleeve 66 of tissue growth inducing material secured to an exterior surface of the conduit 62."

> Column 5, lines 51-58 – "As discussed more fully in U.S. Pat. No. 5,984,956, the rigid conduit 62 may be provided with tissue-growth producing material 82 adjacent the upper end of the conduit 62 to immobilize the conduit 62 within the myocardium 32. The material 82 surrounds the exterior of the conduit 62 and may be a polyester woven cuff 83 or sintered metal to define pores into which tissue growth from the myocardium may occur."

The present invention is directed to having the drug eluting devices present in the internal conduit (not externally wrapped around the conduit). Tweden specifically requires the external wrap for delivering of drugs to facilitate external tissue in growth to the external portion of the device in order to stabilize it into the tissue. Other than the central shaft, no apertures penetrate the conduit of Tweden et al.

As previously described, Tweden focuses on a wrap that externally goes around the conduit. Applicants particular added to the claims that the occlusion-resistant materials that are released internally from the elongated conduit.

As the Examiner points out, Tweden does have one paragraph at column 17, lines 49-62 where different modes of use of the therapeutic agent are suggested, but this hardly stands as an enabling teaching of how to make and use each of the suggestions. Nor does Tweden teach a plurality of apertures in the device. Applicants claimed device provides for a plurality of apertures to drain excess fluid from the region while helping to prevent the drainage tube from clogging, whereas the Tweden device is to provide a shunt around a clogged artery, and an external wrap to facilitate in growth of the device into the surround tissue.

In view of the amendments and supporting arguments, Applicants believe they have adequately distinguished the claimed device over Tweden et al. and respectfully request the present rejection under 35 USC §102 removed.

35 USC § 103 – Kraus in View of Tweden

Claims 2, 4, 5, 19, 21, 22, 33, 35, 36, 51, 53, and 54 were rejected under 35 U .S .C. 103(a) as being unpatentable over US 5,928,182 to Kraus in view of US 7,008,397 to Tweden.

In the specification and figures, Kraus was cited for disclosing a shunt comprising a conduit with inflow and outflow ends (see FIG 6A) that comprises a valve to control fluid flow and that may be made of silicone or polyurethane in order to enhance biocompatibility (see column 3, lines 15-30, column 6, lines 45-57). Kraus fails to disclose that the shunt comprises various therapeutic materials . However, Tweden discloses a shunt (see rejection above) that incorporates therapeutic materials in order to resist occlusion of the shunt (see Tweden, column 1, lines 43-54) . Therefore, the Examiner concludes it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the therapeutic materials disclosed by Tweden to the shunt disclosed by Kraus in order to resist occlusion of the shunt, as taught by Tweden.

The device of Kraus, like the device of Tweden, is a solid catheter conduit. Kraus contains biocompatible materials of silicone or polyurethane, but does not have a plurality of pores in the conduction tube. To move CSF fluid, Kraus relies on the presence of a stepper motor to assist movement within the sealed port. Further, as previously described in Tweden, Tweden's primary enabled description is for an external wrap that can provide drug delivery for tissue in growth – but not as an enabled teaching for internal delivery, particularly where a plurality of apertures are present in the conduit.

In view of the amendments and supporting arguments, Applicants believe they have adequately distinguished the claimed device over Tweden et al. and respectfully request the present rejection under 35 USC §103(a) removed.

35 USC § 103 – Hunter in view of Tweden

Claims 8-10, 25-27, 39-41, and 57-59 are rejected under 35 U .S .C . 103(a) as being unpatentable over US 7,008,397 to Tweden in view of US 2005/0208095 Al to Hunter et al.

In the specification and figures, Tweden was cited for disclosing the device and method substantially as claimed by applicant (see rejection above) with the exception of incorporating mycophenolic acid as a therapeutic agent within the shunt. With regard to claims 8, 9, 25, 26, 39, 40, 57, and 58, Hunter discloses a method of treating patients with various conditions by providing an implantable medical device comprising a therapeutic agent into a patient and allowing the therapeutic agent to elute into the patient (see, generally, paragraph 0014). In an embodiment, the therapeutic material may comprise mycophenolic acid in order to inhibit fibrosis (see paragraph 0223). It has been held to be within the general skill of a worker in the art to select a known material on the basis of its

suitability for the intended use as a matter of obvious design choice. See MPEP 2144 .07. Therefore, the Examiner concludes it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shunt disclosed by Tweden with the therapeutic agent disclosed by Hunter in order to provide the desired therapeutic result, inhibit fibrosis, as taught by Hunter.

With regard to applicant's claims 10, 27,41, and 59, drawn to a "combination" of mycophenolic acid and another agent, applicant fails to specify the amounts of the combination. A mixture of 100% mycophenolic acid and 0% other agents may comprise a combination, giving the term "combination" its broadest reasonable interpretation.

The Examiner has cited Hunter for its teaching of mycophenolic acid as a therapeutic agent within a shunt. That said, combining Hunter in view of Tweden, as previously discussed, fails to teach an operable internal drug delivery system in combination with a shunt containing a plurality of apertures. For the reasons previously given, Applicants respectfully request the obviousness rejection over Hunter in view of Tweden et al. be withdrawn.

35 USC § 103 – Art of Record Not Relied Upon

The Examiner made two pieces of prior art of record and not relied upon but was considered pertinent to applicant's disclosure:

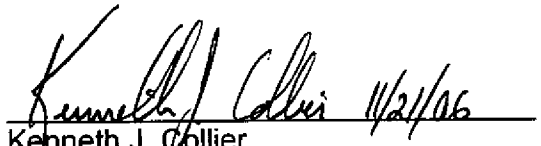
a. US 6,663,881 Kunz et al
   i. Shunts incorporating therapeutic agents
b. US 2004/0147871 Al Burnett
   ii. Implantable shunt with valve and drug eluting properties

Applicants have reviewed both the Kunz et al. reference and that of Burnett. Both Kunz and Burnett do not teach drug delivery from a shunt having a plurality of apertures. Kuntz et al. appears only to teach a number of pharmaceuticals for inhibiting stenosis or restenosis with no particular device structures in mind, whereas Burnett teaches a closed pumping system for relieving abnormal pressures at the site. Applicants argue that neither these teachings in combination with the previous cited references provide the required elements to anticipate or render obvious Applicants claimed invention.

In view of the present claims and arguments, Applicants respectfully request the present application be allowed to issue.

Respectfully submitted for,

Koullick et al.



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PENDING CLAIMS AS AMENDED (MARKED-UP VERSION)

1. (currently amended) An occlusion resistant medical shunt for at least partial implantation into a patient, said shunt comprising an elongated conduit having a lumen therethrough, a proximal end for receipt of bodily fluids for flow through said shunt and a distal end for discharge of said bodily fluids from said shunt, a plurality of aperatures at the proximal end of said shunt, said shunt further including one or more occlusion-resistant materials that are released internally from the elongated conduit to resist occlusion of the lumen of the shunt.

2. (original) The occlusion resistant medical shunt of claim 1 wherein the shunt further includes at least one valve.

3. (original) The occlusion resistant medical shunt of claim 1 wherein the elongated conduit includes one or more elastomeric materials selected from the group consisting of poly(L-lactic acid), poly(lactide-co-glycolide), poly(hydroxybutyrate-co-valerate), silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers, polyethylene, polypropylene, polycarbonate, polysulfone, cellulosics, polydimethylsiloxanes, methylhydrosiloxane-dimethylsiloxane copolymers, polymethylhydrosiloxanes, polyethylhydrosiloxanes, hydride terminated polyphenyl-(dimethylhydrosiloxy)siloxanes, methylhydrosiloxane-phenylmethylsiloxane copolymers, N-vinylpyrrolidone/methyl methacrylate copolymers, 2-hydroxyethylacrylate (e.g. polymacon), various copolymers of 2-hydroxyethylmethacrylate (e.g. hafilcon A and B, vifilcon A, tetrafilcon, dimefilcon, bufilcon, perfilcon, etc.), copolymers of N-vinylpyrrolidone (e.g. lidofilcon A and B, scafilcon A, surfilcon, vifilcon, filcon YA, etc.), polyamides, polyimides, fluoropolymers, polytetrafluoroethylenes, natural rubber and polyisoprene.

4. (original) The occlusion resistant medical shunt of claim 1 wherein the elongated conduit comprises a silicone elastomer material.

5. (original) The occlusion resistant medical shunt of claim 1 wherein the elongated conduit comprises polyurethane material.

6. (original) The occlusion resistant medical shunt of claim 1 wherein the occlusion-resistant material includes a material selected from the group of agents consisting of immunosuppressives, anti-inflammatories, anti-neoplastics, radiation emitting materials, anti-angiogenics, anti-coagulants, anti-proliferatives, anti-thrombogenics, anti-oxidants, cyclooxygenase inhibitors, calcium entry blockers, anti-neoplastics, anti-mitotics, anti-microbials, nitric oxide donors, cell cycle inhibitors, anti-cancer agents, anti-arthritis agents, anti-diabetic agents, thrombin inhibitors, thrombolytics, antibiotics, antiviral agents, and gene therapy agents.

7. (original) The occlusion resistant medical shunt of claim 6 wherein the occlusion-resistant material includes a material selected from the group consisting of beta-radiation emitting isotopes, dexamethasone, beclomethasone, cortisone, hydrocortisone, prednisone, methylprednisone, fluorometholone, tranilast, ketoprofen, curcumin, cyclosporin A, deoxyspergualin, FK506, sulindac, myriocin, 2-aminochromone (U-86983), colchicines, pentosan, antisense oligonucleotides, mycophenolic acid, paclitaxel, etoposide, actinomycin D, camptothecin, carmustine, methotrexate, adriamycin, mitomycin, cis-platinum, mitosis inhibitors, vinca alkaloids, tissue growth factor inhibitors, platinum compounds, cytotoxic inhibitors, alkylating agents, antimetabolite agents, tacrolimus, rapamycin, azathioprine, recombinant or monoclonal antibodies to interleukins, T-cells, B-cells, and receptors, bisantrene, retinoic acid, tamoxifen, compounds containing silver, doxorubicin, azacytidine, homoharringtonine, selenium compounds, superoxide-dismutase, interferons, heparin, rapamycin ABT-578 and analogs, homologs, derivatives or combinations of the above group.

8. (original) The occlusion resistant shunt of claim 7 wherein the occlusion resistant material includes a material selected from the group consisting of mycophenolic acid, rapamycin, rapamycin ABT-578, derivatives or combinations thereof.

9. (original) The occlusion resistant shunt of claim 7 wherein the occlusion resistant material includes mycophenolic acid.

10. (original) The occlusion resistant shunt of claim 7 wherein the occlusion resistant material includes a combination of mycophenolic acid and, rapamycin or rapamycin ABT-578.

11. (original) The occlusion resistant medical shunt of claim 1 wherein the occlusion-resistant material is distributed uniformly throughout the shunt.

12. (original) The occlusion resistant medical shunt of claim 1 wherein the occlusion-resistant material is distributed only in drug eluting regions.

13. (original) The occlusion resistant medical shunt of claim 12 wherein different occlusion-resistant materials are used in different drug eluting regions of the shunt.

14. (original) The occlusion resistant medical shunt of claim 1 wherein the occlusion-resistant material is distributed in one or more agent delivery devices.

15. (original) The occlusion resistant medical shunt of claim 14 wherein the agent delivery devices are selected from the group consisting of spheres, cloth, inserts, eluting plugs, seeds, elongated members and combinations thereof.

16. (original) The occlusion resistant medical shunt of claim 1 wherein the occlusion-resistant material is distributed non-uniformly throughout the shunt and in different amounts.

17. (original) The occlusion resistant medical shunt of claim 16 wherein the occlusion-resistant material is released at different rates between different portions of the shunt.

18. (currently amended) An occlusion resistant medical cannula for at least partial implantation into a patient, said cannula comprising an elongated conduit having a lumen therethrough, a proximal end for receipt of bodily fluids for flow through said cannula and a distal end for discharge of said bodily fluids from said cannula, a plurality of aperatures at the proximal end of said cannula,said cannula further including one or more occlusion-resistant

materials that are released internally from one or more agent delivery devices that provide occlusion resistance of the lumen of the cannula.

19. (original) The occlusion resistant medical cannula of claim 18 wherein the cannula further includes at least one valve.

20. (original) The occlusion resistant medical cannula of claim 18 wherein the elongated conduit includes one or more elastomeric materials selected from the group consisting of poly(L-lactic acid), poly(lactide-co-glycolide), poly(hydroxybutyrate-co-valerate), silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers, polyethylene, polypropylene, polycarbonate, polysulfone, cellulosics, polydimethylsiloxanes, methylhydrosiloxane-dimethylsiloxane copolymers, polymethylhydrosiloxanes, polyethylhydrosiloxanes, hydride terminated polyphenyl-(dimethylhydrosiloxy)siloxanes, methylhydrosiloxane-phenylmethylsiloxane copolymers, N-vinylpyrrolidone/methyl methacrylate copolymers, 2-hydroxyethylacrylate (e.g. polymacon), various copolymers of 2-hydroxyethylmethacrylate (e.g. hafilcon A and B, vifilcon A, tetrafilcon, dimefilcon, bufilcon, perfilcon, etc.), copolymers of N-vinylpyrrolidone (e.g. lidofilcon A and B, scafilcon A, surfilcon, vifilcon, filcon YA, etc.), polyamides, polyimides, fluoropolymers, polytetrafluoroethylenes, natural rubber and polyisoprene.

21. (original) The occlusion resistant medical cannula of claim 20 wherein the elongated conduit comprises a silicone elastomer material.

22. (original) The occlusion resistant medical cannula of claim 20 wherein the elongated conduit comprises polyurethane material.

23. (original) The occlusion resistant medical cannula of claim 18 wherein the occlusion-resistant material includes a material selected from the group of agents consisting of immunosuppressives, anti-inflammatories, anti-neoplastics, anti-angiogenics, anti-coagulants, anti-proliferatives, anti-thrombogenics, anti-oxidants, cyclooxygenase inhibitors, calcium entry blockers, anti-neoplastics, anti-mitotics, anti-microbials, nitric oxide donors, cell cycle

inhibitors, anti-cancer agents, anti-arthritis agents, anti-diabetic agents, thrombin inhibitors, thrombolytics, antibiotics, antiviral agents, and gene therapy agents.

24. (original) The occlusion resistant medical cannula of claim 23 wherein the occlusion-resistant material includes a material selected from the group consisting of beta-radiation emitting isotopes, dexamethasone, beclomethasone, cortisone, hydrocortisone, prednisone, methylprednisone, fluorometholone, tranilast, ketoprofen, curcumin, cyclosporin A, deoxyspergualin, FK506, sulindac, myriocin, 2-aminochromone (U-86983), colchicines, pentosan, antisense oligonucleotides, mycophenolic acid, paclitaxel, etoposide, actinomycin D, camptothecin, carmustine, methotrexate, adriamycin, mitomycin, cis-platinum, mitosis inhibitors, vinca alkaloids, tissue growth factor inhibitors, platinum compounds, cytotoxic inhibitors, alkylating agents, antimetabolite agents, tacrolimus, rapamycin, azathioprine, recombinant or monoclonal antibodies to interleukins, T-cells, B-cells, and receptors, bisantrene, retinoic acid, tamoxifen, compounds containing silver, doxorubicin, azacytidine, homoharringtonine, selenium compounds, superoxide-dismutase, interferons, heparin, rapamycin ABT-578 and analogs, homologs, derivatives or combinations of the above group.

25. (original) The occlusion resistant medical cannula of claim 24 wherein the occlusion resistant material includes a material selected from the group consisting of mycophenolic acid, rapamycin, rapamycin ABT-578, derivatives or combinations thereof.

26. (original) The occlusion resistant shunt of claim 25 wherein the occlusion resistant material includes mycophenolic acid.

27. (original) The occlusion resistant shunt of claim 25 wherein the occlusion resistant material is a combination of mycophenolic acid and rapamycin or rapamycin ABT-578.

28. (original) The occlusion resistant medical cannula of claim 18 wherein different occlusion-resistant materials are used in different agent delivery devices included in the cannula.

29. vThe occlusion resistant medical cannula of claim 18 wherein the agent delivery devices are selected from the group consisting of spheres, cloth, inserts, eluting plugs, seeds, elongated members and combinations thereof.

30. (original) The occlusion resistant medical cannula of claim 18 wherein the occlusion-resistant material is distributed non-uniformly throughout the agent delivery devices and in different amounts.

31. (original) The occlusion resistant medical cannula of claim 30 wherein the occlusion-resistant material is released at different rates between different agent delivery devices of the cannula.

32. (currently amended) A method of preparing an occlusion resistant shunt comprising:

providing an elongated conduit having a lumen therethrough and including a proximal end for receipt of bodily fluids for flow through said shunt and a distal end for discharge of said bodily fluids from said shunt, said conduit having plurality of aperatures at the proximal said shunt,

administering to said shunt one or more occlusion-resistant materials that are released internally from the elongated conduit to resist occlusion of the lumen of said shunt.

33. (original) The method of preparing an occlusion resistant shunt of claim 32 wherein the shunt further includes at least one valve.

34. (original) The method of preparing an occlusion resistant shunt of claim 32 wherein the elongated conduit includes one or more elastomeric materials selected from the group consisting of poly(L-lactic acid), poly(lactide-co-glycolide), poly(hydroxybutyrate-co-valerate), silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers, polyethylene, polypropylene, polycarbonate, polysulfone, cellulosics, polydimethylsiloxanes, methylhydrosiloxane-dimethylsiloxane copolymers, polymethylhydrosiloxanes, polyethylhydrosiloxanes, hydride terminated polyphenyl-(dimethylhydrosiloxy)siloxanes, methylhydrosiloxane-phenylmethylsiloxane copolymers, N-vinylpyrrolidone/methyl methacrylate copolymers, 2-hydroxyethylacrylate

(e.g. polymacon), various copolymers of 2-hydroxyethylmethacrylate (e.g. hafilcon A and B, vifilcon A, tetrafilcon, dimefilcon, bufilcon, perfilcon, etc.), copolymers of N-vinylpyrrolidone (e.g. lidofilcon A and B, scafilcon A, surfilcon, vifilcon, filcon YA, etc.), polyamides, polyimides, fluoropolymers, polytetrafluoroethylenes, natural rubber and polyisoprene.

35. (original) The method of preparing an occlusion resistant shunt of claim 32 wherein the elongated conduit comprises a silicone elastomer material.

36. (original) The method of preparing an occlusion resistant shunt of claim 32 wherein the elongated conduit comprises polyurethane material.

37. (original) The method of preparing an occlusion resistant shunt of claim 32 wherein the occlusion-resistant material includes a material selected from the group of agents consisting of immunosuppressives, anti-inflammatories, anti-neoplastics, anti-angiogenics, anti-coagulants, anti-proliferatives, anti-thrombogenics, anti-oxidants, cyclooxygenase inhibitors, calcium entry blockers, anti-neoplastics, anti-mitotics, anti-microbials, nitric oxide donors, cell cycle inhibitors, anti-cancer agents, anti-arthritis agents, anti-diabetic agents, thrombin inhibitors, thrombolytics, antibiotics, antiviral agents, and gene therapy agents.

38. (original) The method of preparing an occlusion resistant shunt of claim 37 wherein the occlusion-resistant material includes a material selected from the group consisting of beta-radiation emitting isotopes, dexamethasone, beclomethasone, cortisone, hydrocortisone, prednisone, methylprednisone, fluorometholone, tranilast, ketoprofen, curcumin, cyclosporin A, deoxyspergualin, FK506, sulindac, myriocin, 2-aminochromone (U-86983), colchicines, pentosan, antisense oligonucleotides, mycophenolic acid, paclitaxel, etoposide, actinomycin D, camptothecin, carmustine, methotrexate, adriamycin, mitomycin, cis-platinum, mitosis inhibitors, vinca alkaloids, tissue growth factor inhibitors, platinum compounds, cytotoxic inhibitors, alkylating agents, antimetabolite agents, tacrolimus, rapamycin, azathioprine, recombinant or monoclonal antibodies to interleukins, T-cells, B-cells, and receptors, bisantrene, retinoic acid, tamoxifen, compounds containing silver, doxorubicin, azacytidine,

homoharringtonine, selenium compounds, superoxide-dismutase, interferons, heparin, rapamycin ABT-578 and analogs, homologs, derivatives or combinations of the above group.

39. (original) The method of preparing an occlusion resistant shunt of claim 38 wherein the occlusion resistant material includes a material selected from the group consisting of mycophenolic acid, rapamycin, rapamycin ABT-578, derivatives or combinations thereof.

40. (original) The occlusion resistant shunt of claim 39 wherein the occlusion resistant material includes mycophenolic acid.

41. (original) The occlusion resistant shunt of claim 35 wherein the occlusion resistant material includes a combination of mycophenolic acid and, rapamycin or rapamycin ABT-578.

42. (original) The method of preparing an occlusion resistant shunt of claim 32 wherein the occlusion-resistant material is distributed uniformly throughout the shunt.

43. (original) The method of preparing an occlusion resistant shunt of claim 32 wherein the occlusion-resistant material is distributed only in drug eluting regions.

44. (original) The method of preparing an occlusion resistant shunt of claim 32 wherein the drug eluting regions are selected from the group consisting of the proximal portion, the distal portion, and one or more valves.

45. (original) The method of preparing an occlusion resistant shunt of claim 44 wherein different occlusion-resistant materials are used in different drug eluting regions of the shunt.

46. (original) The method of preparing an occlusion resistant shunt of claim 32 wherein the occlusion-resistant material is distributed in one or more agent delivery devices.

47. (original) The method of preparing an occlusion resistant shunt of claim 46 wherein the agent delivery devices are selected from the group consisting of spheres, cloth, inserts, eluting plugs, seeds, elongated members and combinations thereof.

48. (original) The method of preparing an occlusion resistant shunt of claim 32 wherein the occlusion-resistant material is distributed non-uniformly throughout the shunt and in different amounts.

49. (original) The method of preparing an occlusion resistant shunt of claim 48 wherein the occlusion-resistant material is released at different rates between different portions of the shunt.

50. (currently amended) A method of inhibiting the occlusion of an at least partially implanted shunt comprising:

implanting a shunt including an elongated conduit having a lumen therethrough, a proximal end for receipt of bodily fluids for flow through said shunt and a distal end for discharge of said bodily fluids from said shunt, said shunt having a plurality of aperatures at the proximal of said shunt, said shunt further including one or more occlusion-resistant materials; and

releasing from the internal elongated conduit the one or more occlusion-resistant materials to inhibit the occlusion of the lumen of said shunt.

51. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 50 wherein the shunt further includes at least one valve.

52. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 50 wherein the elongated conduit includes one or more elastomeric materials selected from the group consisting of poly(L-lactic acid), poly(lactide-co-glycolide), poly(hydroxybutyrate-co-valerate), silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers, polyethylene, polypropylene, polycarbonate, polysulfone, cellulosics, polydimethylsiloxanes, methylhydrosiloxane-dimethylsiloxane copolymers, polymethylhydrosiloxanes,

polyethylhydrosiloxanes, hydride terminated polyphenyl-(dimethylhydrosiloxy)siloxanes, methylhydrosiloxane-phenylmethylsiloxane copolymers, N-vinylpyrrolidone/methyl methacrylate copolymers, 2-hydroxyethylacrylate (e.g. polymacon), various copolymers of 2-hydroxyethylmethacrylate (e.g. hafilcon A and B, vifilcon A, tetrafilcon, dimefilcon, bufilcon, perfilcon, etc.), copolymers of N-vinylpyrrolidone (e.g. lidofilcon A and B, scafilcon A, surfilcon, vifilcon, filcon YA, etc.), polyamides, polyimides, fluoropolymers, polytetrafluoroethylenes, natural rubber and polyisoprene.

53. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 50 wherein the elongated conduit comprises a silicone elastomer material.

54. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 50 wherein the elongated conduit comprises polyurethane material.

55. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 50 wherein the occlusion-resistant material is selected from the group of agents consisting of immunosuppressives, anti-inflammatories, anti-neoplastics, anti-angiogenics, anti-coagulants, anti-proliferatives, anti-thrombogenics, anti-oxidants, cyclooxygenase inhibitors, calcium entry blockers, anti-neoplastics, anti-mitotics, anti-microbials, nitric oxide donors, cell cycle inhibitors, anti-cancer agents, anti-arthritis agents, anti-diabetic agents, thrombin inhibitors, thrombolytics, antibiotics, antiviral agents, and gene therapy agents.

56. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 55 wherein the occlusion-resistant material includes a material selected from the group consisting of beta-radiation emitting isotopes, dexamethasone, beclomethasone, cortisone, hydrocortisone, prednisone, methylprednisone, fluorometholone, tranilast, ketoprofen, curcumin, cyclosporin A, deoxyspergualin, FK506, sulindac, myriocin, 2-aminochromone (U-86983), colchicines, pentosan, antisense oligonucleotides, mycophenolic acid, paclitaxel, etoposide, actinomycin D, camptothecin, carmustine, methotrexate, adriamycin, mitomycin, cis-platinum, mitosis inhibitors, vinca alkaloids, tissue growth factor inhibitors, platinum compounds, cytotoxic inhibitors, alkylating agents, antimetabolite

agents, tacrolimus, rapamycin, azathioprine, recombinant or monoclonal antibodies to interleukins, T-cells, B-cells, and receptors, bisantrene, retinoic acid, tamoxifen, compounds containing silver, doxorubicin, azacytidine, homoharringtonine, selenium compounds, superoxide-dismutase, interferons, heparin, rapamycin ABT-578 and analogs, homologs, derivatives or combinations of the above group.

57. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 56 wherein the occlusion resistant material includes a material selected from the group consisting of mycophenolic acid, rapamycin, rapamycin ABT-578, derivatives or combinations thereof.

58. (original) The occlusion resistant shunt of claim 57 wherein the occlusion resistant material includes mycophenolic acid.

59. (original) The occlusion resistant shunt of claim 51 wherein the occlusion resistant material includes a combination of mycophenolic acid and, rapamycin or rapamycin ABT-578.

60. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 50 wherein the occlusion-resistant material is distributed uniformly throughout the shunt.

61. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 50 wherein the occlusion-resistant material is distributed only in drug eluting regions.

62. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 50 wherein the drug eluting regions are selected from the group consisting of the proximal portion, the distal portion, and one or more valves.

63. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 62 wherein different occlusion-resistant materials are used in different drug eluting regions of the shunt.

64. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 50 wherein the occlusion-resistant material is distributed in one or more agent delivery devices.

65. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 64 wherein the agent delivery devices are selected from the group consisting of spheres, cloth, inserts, eluting plugs, seeds, elongated members and combinations thereof.

66. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 50 wherein the occlusion-resistant material is distributed non-uniformly throughout the shunt and in different amounts.

67. (original) The method of inhibiting the occlusion of an at least partially implanted shunt of claim 66 wherein the occlusion-resistant material is released at different rates between different portions of the shunt.